

Critical revision of the article: CO, AH, NB, MW, NH, MB, LN

Final approval of the article: CO, LN

Statistical analysis: NH

Obtained funding: CO

Overall responsibility: CO

## REFERENCES

- Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation* 2006;113:e463-4.
- Kent KC, Bartek S, Kuntz KM, Anninos E, Skillman JJ. Prospective study of wound complications in continuous infrainguinal incisions after lower limb arterial reconstruction: incidence, risk factors, and cost. *Surgery* 1996;119:378-83.
- Nguyen LL, Brahmanandam S, Bandyk DF, Belkin M, Clowes AW, Moneta GL, et al. Female gender and oral anticoagulants are associated with wound complications in lower extremity vein bypass: an analysis of 1404 operations for critical limb ischemia. *J Vasc Surg* 2007;46:1191-7.
- Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *Am J Infect Control* 1999;27:97-132; quiz 133-4; discussion: 96.
- Alexander JW, Solomkin JS, Edwards MJ. Updated recommendations for control of surgical site infections. *Ann Surg* 2011;253:1082-93.
- Wilkinson LJ, White RJ, Chipman JK. Silver and nanoparticles of silver in wound dressings: a review of efficacy and safety. *J Wound Care* 2011;20:543-9.
- Childress BB, Berceli SA, Nelson PR, Lee WA, Ozaki CK. Impact of an absorbent silver-cluting dressing system on lower extremity revascularization wound complications. *Ann Vasc Surg* 2007;21:598-602.
- Khuri SF, Daley J, Henderson W, Hur K, Demakis J, Aust JB, et al. The Department of Veterans Affairs' NSQIP: the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. National VA Surgical Quality Improvement Program. *Ann Surg* 1998;228:491-507.
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377-81.
- Turtiainen J, Saimanen E, Partio T, Karkkainen J, Kiviniemi V, Mäkinen K, et al. Surgical wound infections after vascular surgery: prospective multicenter observational study. *Scand J Surg* 2010;99:167-72.
- McPhee JT, Nguyen LL, Ho KJ, Ozaki CK, Conte MS, Belkin M. Risk prediction of 30-day readmission after infrainguinal bypass for critical limb ischemia. *J Vasc Surg* 2013;57:1481-8.
- Jauhari YA, Hughes CO, Black SA, Jones KG, Hinchliffe RJ, Thompson MM, et al. Endoscopic vein harvesting in lower extremity arterial bypass: a systematic review. *Eur J Vasc Endovasc Surg* 2014;47:621-39.
- Krieger BR, Davis DM, Sanchez JE, Mateka JJ, Nfonang VN, Frattini JC, et al. The use of silver nylon in preventing surgical site infections following colon and rectal surgery. *Dis Colon Rectum* 2011;54:1014-9.
- Biffi R, Fattori L, Bertani E, Radice D, Rotmensz N, Misitano P, et al. Surgical site infections following colorectal cancer surgery: a randomized prospective trial comparing common and advanced antimicrobial dressing containing ionic silver. *World J Surg Oncol* 2012;10:94.
- Galli MM, Protzman NM, Brigido SA. Utilization of silver hydrogel sheet dressing on postsurgical incisions: a pilot study in foot and ankle surgery. *Foot Ankle Spec* 2013;6:422-33.
- Giles KA, Hamdan AD, Pomposelli FB, Wyers MC, Siracuse JJ, Schermerhorn ML. Body mass index: surgical site infections and mortality after lower extremity bypass from the National Surgical Quality Improvement Program 2005-2007. *Ann Vasc Surg* 2010;24:48-56.
- Greenblatt DY, Rajamanickam V, Mell MW. Predictors of surgical site infection after open lower extremity revascularization. *J Vasc Surg* 2011;54:433-9.
- Conte MS, Bandyk DF, Clowes AW, Moneta GL, Seely L, Lorenz TJ, et al. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. *J Vasc Surg* 2006;43:742-51; discussion: 751.

Submitted Jun 11, 2014; accepted Jul 22, 2014.

*Additional material for this article may be found online at [www.jvascsurg.org](http://www.jvascsurg.org).*

## DISCUSSION

**Dr Jon Matsumura** (*Madison, Wisc*). What other process measures were in place to address wound complications during the study? Methicillin-resistant *Staphylococcus aureus* screening, normothermia, antibiotic selection and timing?

**Dr C. Keith Ozaki**. Over the last decade, we have had many changes and redesign of our care processes to address these issues. More attention to normothermia, more attention to timely perioperative antibiotics, increased considerations of approaches, such as skip incisions, all of those continued to be implemented over time and may account for some of the differences between the current report and the prior nonconcurrent study that had the original control group first and then at a later date had the silver alginate dressing cohort.

There were a variety of wound practices at these three different institutions, so I cannot summarize those in just a few statements. But we did try to design this trial to be applicable to several different settings, both the civilian and the Veterans Administration population.

**Dr Peter Lawrence** (*Los Angeles, Calif*). Did you classify wounds by degree of contamination? Clean contaminated wounds in patients with foot infections might benefit from this dressing, while the average clean wound would not. Did you calculate the cost/benefit for each group?

**Dr Ozaki**. That is an excellent point. The cost data related to this, especially the cost of having a wound complication, will be presented at Eastern Vascular and New England meetings this fall. These dressings are actually quite inexpensive. For a 4-by-5 inch piece, the actual General Services Administration price, and that translates pretty well to the civilian price, is less than \$10.00. We tested an approach that we thought might be cost-effective even if there was a very small clinical benefit. Whenever we broke the cases down into those that were nonclean, we actually by  $\chi^2$  analysis did see a statistically significant benefit for the silver dressing. I did not present those data though because I do not trust the data. Half of those cases were labeled as clean-contaminated. And by the technical definition, that means you either enter a hollow viscus or you have a



clear break in sterile technique. So I am concerned about the primary quality of that information.

But you are correct, from our data set we should be able to select patients most at risk, and maybe for that select population there could be a role for this type of dressing.

**Dr David Yu** (*Seattle, Wash*). I was wondering if the immunocompetence status of these patients were taken into consideration for the study?

**Dr Ozaki.** I do not have any specific assays of immune status. We did have a subset of the patients that were on immunosuppressive prednisone, and there was no differential in the wound complication rates for these patients.

**Dr Jens Eldrup-Jorgensen** (*Portland, Me*). Surgical site infections in our institution have received a lot of scrutiny of late. I think a lot of the value of this study is to give us a contemporary assessment of what realistic surgical site infection rates are. We find that in our institution they are very similar to what you are reporting here, and yet the expectation is that they should be much lower, at least from some parties.

We have also tried using a silver-based dressing on a more empiric approach. And now with the failure of this to show any efficacy, are you trialing the negative-pressure dressings in some of these more complex wounds?

**Dr Ozaki.** Based on some of the earlier reports, I am intrigued by the negative-pressure dressings even for the closed incisions. That technique warrants further investigation. Actual infection rates are in the midteens for our lower extremity revascularizations and 6.6% when you have to cut down to do an endovascular aneurysm repair. I think that is useful data, and I think it is real. All our study institutions had these rates.

**Dr Cassius Iyad Ochoa Chaar** (*New Haven, Conn*). I congratulate you on doing a study that is sponsored by industry but still have data independently analyzed with the investigators. What were the lengths of those incisions, and were the anatomical locations comparable in both groups? And for the groin specifically, were you able to compare vertical and transverse incisions?

**Dr Ozaki.** The average incision length was just over 32 cm. There was not a difference between the groups in incision length. Regarding the orientation of the groin incision, there were many confounding factors, such as whether this was a redo surgery that had a prior vertical incision, whether this was an obese patient, etc. Most of the endovascular aneurysm repair participants had a transverse groin incision vs those with extensive occlusive disease that needed a long profundoplasty might have had vertical. So I am nervous about analyzing that data under these study conditions because of those confounding factors. However we do have a lot of granularity in the data set with regards to location of incisions, types of incisions, and there will be future analyses of those issues.

**Dr Palma Shaw** (*Syracuse, NY*). Given the number of different silver dressings, with different amounts of silver in each dressing, do you think that there is a role for looking at different amounts of silver and seeing if this has an effect?

**Dr Ozaki.** Yes, that is a great point. There are a variety of silver dressing products. If you talk to another silver dressing manufacturer, they will suggest that the reason your study was negative is because you used the wrong dressing. If there are any industry partners out there thirsty to really look at this, we are anxious to have something that will help these patients.